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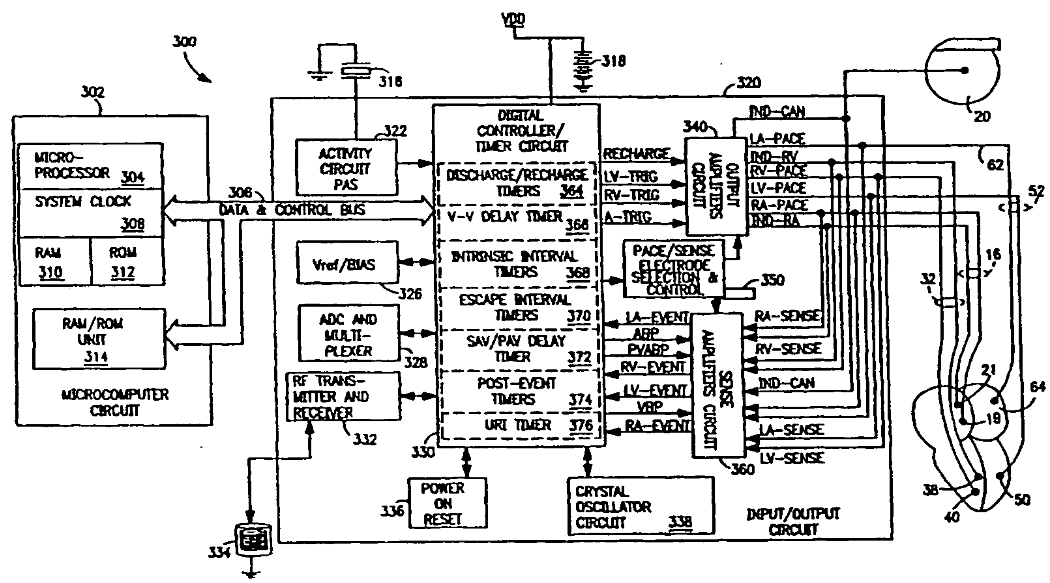
(54) Title: BI-CHAMBER CARDIAC PACING SYSTEM EMPLOYING UNIPOLAR LEFT HEART CHAMBER LEAD IN COMBINATION WITH BIPOLAR RIGHT HEART CHAMBER LEAD



(57) Abstract: Multi-site cardiac pacing systems, including ICD's for pacing right and left heart chambers in inhibited and triggered pacing modes employing combinations of right and left heart chamber pace/sense electrodes for providing left heart chamber pacing and sensing to facilitate placement of the left heart chamber pace/sense electrode at a left heart chamber pace/sense site that is difficult to access. In a bi-ventricular pacing system, an implantable pulse generator optionally having an IPG indifferent electrode is coupled to a small diameter, unipolar, left ventricular (LV) lead and a bipolar right ventricular (RV) lead. The LV lead is advanced through the superior vena cava, the right atrium, the ostium of the coronary sinus (CS), the CS, and into a coronary vein descending from the CS to locate the LV active pace/sense electrode at a desired LV pace/sense site. An LV lead placed on an epicardial

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BI-CHAMBER CARDIAC PACING SYSTEM EMPLOYING UNIPOLAR LEFT HEART CHAMBER LEAD IN COMBINATION WITH BIPOLAR RIGHT HEART CHAMBER LEAD

FIELD OF THE INVENTION

The present invention pertains to multi-site cardiac pacing systems for pacing right and left heart chambers in inhibited and triggered pacing modes employing combinations of right and left heart chamber pace/sense electrodes for providing left heart chamber pacing and sensing to facilitate placement of the left heart chamber pace/sense electrode at a left heart chamber pace/sense site that is difficult to access.

BACKGROUND OF THE INVENTION

In diseased hearts having conduction defects and in congestive heart failure (CHF), cardiac depolarizations that naturally occur in one upper or lower heart chamber are not conducted in a timely fashion either within the heart chamber or to the other upper or lower heart chamber. In patients suffering from CHF, the hearts may become dilated, and the conduction and depolarization sequences of the heart chambers may exhibit Intra-Atrial Conduction Defects (IACD), Left Bundle Branch Block (LBBB), Right Bundle Branch Block (RBBB), and Intra Ventricular Conduction Defects (IVCD). In such cases, the right and left heart chambers do not contract in optimum synchrony with each other, and cardiac output suffers due to the conduction defects. In addition, spontaneous depolarizations of the left atrium or left ventricle occur at ectopic foci in these left heart chambers, and the natural activation sequence is grossly disturbed. In such cases, cardiac output deteriorates because the contractions of the right and left heart chambers are not synchronized sufficiently to eject blood therefrom. Furthermore, significant conduction disturbances between the right and left atria can result in left atrial flutter or fibrillation.

depolarizations of the right heart chamber is effected between right heart chamber active tip and indifferent ring electrodes on the bipolar right heart lead. Sensing of the left heart chamber depolarizations is effected between a single left heart chamber active tip pace/sense electrode and the right heart chamber active tip pace/sense electrode. Then, sensing is switched to a unipolar mode to determine the true chamber of origin of the sensed left heart depolarization. Right and left heart chamber pacing to the other heart chamber is effected in a unipolar manner, employing the IPG housing or canister as an indifferent IPG "can" electrode.

In the above-incorporated '970 patent, bipolar left and right heart chamber pacing leads are employed that are coupled to a single sense amplifier and pacing output amplifier for sensing right and left heart depolarizations and providing right and left heart chamber pacing pulses. When sensing, the right and left heart chamber active tip pace/sense electrodes are coupled together to one input of the sense amplifier, and the right and left heart chamber indifferent ring pace/sense electrodes are coupled together to the other input of the sense amplifier. When pacing the right heart chamber, the right and left heart chamber indifferent ring pace/sense electrodes are coupled together, and a low energy pacing pulse is delivered through the right heart chamber active tip electrode. When pacing the left heart chamber, the right and left heart chamber indifferent ring pace/sense electrodes are coupled together, and a high energy pacing pulse is delivered through both the right and left heart chamber active tip electrodes. The pacing pulse energy is distributed along multiple pacing vectors, and in fact both the right and left heart chambers are simultaneously paced.

It is important that pacing energy be directed in a vector that maximizes efficiency of capturing the heart. In addition, the location of a left ventricular distal active pace/sense electrode deep in a cardiac vein within the narrow vessel lumen necessitates use of very small diameter unipolar lead bodies that do not allow inclusion of an indifferent ring electrode and associated lead conductor and insulation separating it from the lead conductor for the active pace/sense electrode. Since the active pace/sense electrode is separated from direct contact with the left ventricular myocardium, the left ventricular pacing threshold is likely to be higher than the right

RHC indifferent pace/sense electrode, whereby the LHC pacing vector traverses the mass of the LHC.

In a bi-ventricular pacing system, a small diameter, unipolar, left ventricular, coronary sinus (LV CS) endocardial lead and a bipolar right ventricular (RV) endocardial lead are preferably employed to provide the LHC and RHC pace/sense electrodes. The LV CS lead is advanced through the superior vena cava, the right atrium, the ostium of the coronary sinus (CS), the CS, and into a coronary vein descending from the CS to locate the LV active pace/sense electrode at a desired LV pace/sense site. The RV lead is advanced into the RV chamber to locate RV active and indifferent pace/sense electrodes therein. Sensing of RV spontaneous cardiac depolarizations to provide a RV sense event signal and delivery of RV pacing pulses is conducted across the RV active pace/sense electrode and one of the RV or IPG indifferent pace/sense electrodes. Sensing of LV spontaneous cardiac depolarizations to provide a LV sense event signal is conducted in a unipolar sensing vector across the LV active pace/sense electrode and the IPG indifferent pace/sense electrode or in a trans-ventricular sensing vector across the LV active pace/sense electrode and one of the RV active or indifferent pace/sense electrodes. Delivery of LV pacing pulses is conducted across the LV active pace/sense electrode and the RV indifferent pace/sense electrode and in a pacing vector that encompasses the bulk of the LV.

In a bi-atrial pacing system, a unipolar, left atrial, coronary sinus (LA CS) lead and a bipolar right atrial (RA) endocardial lead are preferably employed to provide the LHC and RHC pace/sense electrodes. Use of epicardial leads is of course an option. The unipolar LA CS(or epicardial) lead locates an active LA pace/sense electrode in relation to the LA, and the bipolar RA lead locates an active RA pace/sense electrode and indifferent RA pace/sense electrode in relation to the RA. Sensing of LA spontaneous cardiac depolarizations to provide a LA sense event signal is conducted across the LA active pace/sense electrode and one of the RA active or indifferent pace/sense electrodes or the IPG indifferent pace/sense electrodes. Delivery of LA pacing pulses is conducted across the LA active pace/sense electrode and the RA

These and other advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

FIG. 1 is an illustration of transmission of the cardiac depolarization waves through the heart in a normal electrical activation sequence;

FIG. 2 is a schematic diagram depicting a three channel, atrial and bi-ventricular, pacing system in which the present invention is preferably implemented;

FIG. 3 is a simplified block diagrams of one embodiment of IPG circuitry and associated leads employed in the system of FIG. 2 for providing four pacing channels that are selectively programmed in bi-atrial and/or bi-ventricular pacing modes;

FIG. 4 is a comprehensive flow-chart illustrating the operating modes of the IPG circuitry of FIG. 3 in a variety of AV synchronous, bi-ventricular pacing modes in accordance with one embodiment of the invention;

FIG. 5 is a flow chart illustrating the steps of delivering ventricular pacing pulses following time-out of an AV delay in FIG. 4;

FIG. 6A-6B is a flow chart illustrating the steps of delivering ventricular pacing pulses following a ventricular sense event during the time-out of an AV delay or the V-A escape interval in FIG. 4; and

FIG. 7 is a comprehensive flow-chart illustrating the operating modes of the IPG circuitry of FIG. 3 in a variety of bi-atrial or bi-ventricular pacing modes in accordance with a further embodiment of the invention selectively employing steps of FIGs. 5 and 6 therein.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following detailed description, references are made to illustrative embodiments for carrying out the invention. It is understood that other embodiments may be utilized without departing from the scope of the invention. For example, the invention is disclosed in detail in FIGs. 2 and 3 in the context of an AV sequential, bi-

wave appears as the P-wave of the PQRST complex when sensed across external ECG electrodes and displayed. The component of the atrial depolarization wave passing between a pair of unipolar or bipolar pace/sense electrodes, respectively, located on or adjacent the RA or LA is also referred to as a sensed P-wave. Although the location and spacing of the external ECG electrodes or implanted unipolar atrial pace/sense electrodes has some influence, the normal P-wave width does not exceed 80 msec in width as measured by a high impedance sense amplifier coupled with such electrodes. A normal near field P-wave sensed between closely spaced bipolar pace/sense electrodes and located in or adjacent the RA or the LA has a width of no more than 60 msec as measured by a high impedance sense amplifier.

The depolarization impulse that reaches the AV Node is distributed inferiorly down the bundle of His in the intraventricular septum after a delay of about 120 msec. The depolarization wave reaches the apical region of the heart about 20 msec later and then travels superiorly though the Purkinje Fiber network over the remaining 40 msec. The aggregate RV and LV depolarization wave and the subsequent T-wave accompanying re-polarization of the depolarized myocardium are referred to as the QRST portion of the PQRST cardiac cycle complex when sensed across external ECG electrodes and displayed. When the amplitude of the QRS ventricular depolarization wave passing between a bipolar or unipolar pace/sense electrode pair located on or adjacent the RV or LV exceeds a threshold amplitude, it is detected as a sensed R-wave. Although the location and spacing of the external ECG electrodes or implanted unipolar ventricular pace/sense electrodes has some influence, the normal R-wave width does not exceed 80 msec in width as measured by a high impedance sense amplifier. A normal near field R-wave sensed between closely spaced bipolar pace/sense electrodes and located in or adjacent the RV or the LV has a width of no more than 60 msec as measured by a high impedance sense amplifier.

The typical normal conduction ranges of sequential activation are also described in the article by Durrer et al., entitled "Total Excitation of the Isolated Human Heart", in CIRCULATION (Vol. XLI, pp. 899-912, June 1970). This normal electrical activation sequence becomes highly disrupted in patients suffering from

functions. The depicted positions in or about the right and left heart chambers are also merely exemplary. For instance, any of the leads may be placed epicardially if desired, or there may be other arrangements made. Moreover other leads and pace/sense electrodes may be used instead of the depicted leads and pace/sense electrodes that are adapted to be placed at electrode sites on or in or relative to the RA, LA, RV and LV.

The depicted bipolar endocardial RA lead 16 is passed through a vein into the RA chamber of the heart 10, and the distal end of the RA lead 16 is attached to the RA wall by an attachment mechanism 17. The bipolar endocardial RA lead 16 is formed with an in-line connector 13 fitting into a bipolar bore of IPG connector block 12 that is coupled to a pair of electrically insulated conductors within lead body 15 and connected with distal tip RA pace/sense electrode 19 and proximal ring RA pace/sense electrode 21. Delivery of atrial pace pulses and sensing of atrial sense events is effected between the distal tip RA pace/sense electrode 19 and proximal ring RA pace/sense electrode 21, wherein the proximal ring RA pace/sense electrode 21 functions as an indifferent electrode (IND_RA). Alternatively, a unipolar endocardial RA lead could be substituted for the depicted bipolar endocardial RA lead 16 and be employed with the IND_CAN electrode 20. Or, one of the distal tip RA pace/sense electrode 19 and proximal ring RA pace/sense electrode 21 can be employed with the IND_CAN electrode 20 for unipolar pacing and/or sensing.

Bipolar, endocardial RV lead 32 is passed through the vein and the RA chamber of the heart 10 and into the RV where its distal ring and tip RV pace/sense electrodes 38 and 40 are fixed in place in the apex by a conventional distal attachment mechanism 41. The RV lead 32 is formed with an in-line connector 34 fitting into a bipolar bore of IPG connector block 12 that is coupled to a pair of electrically insulated conductors within lead body 36 and connected with distal tip RV pace/sense electrode 40 and proximal ring RV pace/sense electrode 38, wherein the proximal ring RV pace/sense electrode 38 functions as an indifferent electrode (IND_RV). Alternatively, a unipolar endocardial RV lead could be substituted for the depicted bipolar endocardial RV lead 32 and be employed with the IND_CAN electrode 20.

the RA would be accomplished along the pacing vector between the active proximal LA CS active electrode and the proximal ring RA indifferent pace/sense electrode 21.

FIG. 3 depicts bipolar RA lead 16, optional unipolar LA lead 62, bipolar RV lead 32, and unipolar LV CS lead 52 coupled with an IPG circuit 300 having programmable modes and parameters and a telemetry transceiver of a DDDR type known in the pacing art. A unipolar LA pace/sense electrode 64 is provided at the distal end of the LA CS lead 62. The unipolar LA lead 62 may also be a CS lead and may be formed as part of the LV CS lead 52 as described above. The IPG circuit 300 is illustrated in a functional block diagram divided generally into a microcomputer circuit 302 and a pacing circuit 320. The pacing circuit 320 includes the digital controller/timer circuit 330, the output amplifiers circuit 340, and the sense amplifiers circuit 360, as well as a number of other circuits and components described below.

Crystal oscillator circuit 338 provides the basic timing clock for the pacing circuit 320, while battery 318 provides power. Power-on-reset circuit 336 responds to initial connection of the circuit to the battery for defining an initial operating condition and similarly, resets the operative state of the device in response to detection of a low battery condition. Reference mode circuit 326 generates stable voltage reference and currents for the analog circuits within the pacing circuit 320, while analog to digital converter ADC and multiplexer circuit 328 digitizes analog signals and voltage to provide real time telemetry if a cardiac signals from sense amplifiers 360, for uplink transmission via RF transmitter and receiver circuit 332. Voltage reference and bias circuit 326, ADC and multiplexer 328, power-on-reset circuit 336 and crystal oscillator circuit 338 may correspond to any of those presently used in current marketed implantable cardiac pacemakers.

If the IPG is programmed to a rate responsive mode, the signals output by one or more physiologic sensor are employed as a rate control parameter (RCP) to derive a physiologic escape interval. For example, the escape interval is adjusted proportionally the patient's activity level developed in the patient activity sensor (PAS) circuit 322 in the depicted, exemplary IPG circuit 300. The patient activity sensor 316 is coupled to the implantable pulse generator housing 118 and may take

application-specific, hardwired logic, or state-machine type circuit may perform the functions of microprocessor 304.

Digital controller/timer circuit 330 operates under the general control of the microcomputer 302 to control timing and other functions within the pacing circuit 320 and includes a set of timing and associated logic circuits of which certain ones pertinent to the present invention are depicted. The depicted timing circuits include discharge/recharge timers 364, V-V delay timer 366, an intrinsic interval timer 368 for timing elapsed V-EVENT to V-EVENT intervals or V-EVENT to A-EVENT intervals, escape interval timers 370 for timing A-A, V-A, and/or V-V pacing escape intervals, an AV delay interval timer 372 for timing an AV delays from a preceding A-EVENT (SAV) or A-PACE (PAV), a post-ventricular timer 374 for timing post-ventricular time periods, and an upper rate interval (URI) timer 376. RHC pace trigger and sense events are typically used for starting and resetting these intervals and periods. However, it would be possible to allow the physician to select and program LHC pace trigger and sense events for these timing purposes.

Microcomputer 302 controls the operational functions of digital controller/timer circuit 330, specifying which timing intervals are employed, and setting at least the programmed-in base timing intervals, via data and control bus 306. Digital controller/timer circuit 330 starts and times out these intervals and delays for controlling operation of the atrial and ventricular sense amplifiers in sense amplifiers circuit 360 and the atrial and ventricular pace pulse generators in output amplifiers circuit 340.

The post-event timers 374 time out the post-ventricular time periods following an RV-EVENT or LV-EVENT or a RV-PACE or LV-PACE and post-atrial time periods following an A-EVENT or A-PACE. The durations of the post-event time periods may also be selected as programmable parameters stored in the microcomputer 302. The post-ventricular time periods include the PVARP, a post-atrial ventricular blanking period (PAVBP), a ventricular blanking period (VBP), a ventricular refractory period (VRP), and a conditional ventricular refractory period (CVRP). The post-atrial time periods include an atrial refractory period (ARP) during

be designated in pacing and sensing functions. For convenience, the following description separately designates pace and sense electrode pairs where a distinction is appropriate.

The output amplifiers circuit 340 includes switching circuits for coupling selected pace electrode pairs from among the lead conductors and the IND_CAN electrode 20 to the RA pace pulse generator, LA pace pulse generator, RV pace pulse generator and LV pace pulse generator. Pace/sense electrode pair selection and control circuit 350 selects lead conductors and associated pace electrode pairs to be coupled with the atrial and ventricular output amplifiers within output amplifiers circuit 340 for accomplishing RA, LA, RV and LV pacing as described below.

The sense amplifiers circuit 360 contains sense amplifiers corresponding to any of those presently employed in commercially marketed cardiac pacemakers for atrial and ventricular pacing and sensing. As noted in the above-referenced, commonly assigned, `324 patent, it has been common in the prior art to use very high impedance P-wave and R-wave sense amplifiers to amplify the voltage difference signal which is generated across the sense electrode pairs by the passage of a cardiac depolarization. The high impedance sense amplifiers use high gain to amplify the low amplitude signals and rely on pass band filters, time domain filtering and amplitude threshold comparison to discriminate a P-wave or R-wave from background electrical noise. Digital controller/timer circuit 330 controls sensitivity settings of the atrial and ventricular sense amplifiers 360.

The sense amplifiers are uncoupled from the sense electrodes during the blanking periods before, during, and after delivery of a pacing pulse to any of the pace electrodes of the pacing system to avoid saturation of the sense amplifiers. The sense amplifiers circuit 360 includes blanking circuits for uncoupling the selected pairs of the lead conductors and the IND_CAN electrode 20 from the inputs of the RA sense amplifier, LA sense amplifier, RV sense amplifier and LV sense amplifier during the ABP, PVABP and VBP. The sense amplifiers circuit 360 also includes switching circuits for coupling selected sense electrode lead conductors and the IND_CAN electrode 20 to the RA sense amplifier, LA sense amplifier, RV sense amplifier and

electrode (64 and/or 50) and the RHC indifferent ring pace/sense electrode (21 and/or 38), whereby the LHC pacing vector traverses the mass of the LHC.

Advantageously, the pacemaker of FIG. 3 could be simplified by providing only a single atrial sense amplifier coupled to a trans-atrial sense electrode pair comprising the active CS LA and the active RA pace/sense electrodes 64 and 19. Then, only a single A-EVENT would be provided and employed, and it may reflect either a RA-SENSE or a LA-SENSE. Similarly, the pacemaker could be simplified by providing only a single ventricular sense amplifier coupled to the active CS LV and the active distal tip RV pace/sense electrodes 50 and 40 to provide a single trans-ventricular sensing vector. Then, only a single V-EVENT would be provided and employed.

To simplify the description of FIGs. 4 through 6A-6B, it will be assumed that the following references to an "A-EVENT" and "A-PACE" will be the RA-EVENT and RA-PACE, respectively, if there is no LA pacing or sensing provided or programmed on, or will be a programmed one of the RA-EVENT or LA-EVENT and RA-PACE or LA-PACE, respectively. The A-EVENT could also be the output sense event signal of the single atrial sense amplifier coupled to active pace/sense electrodes 19 and 64.

The general operation of IPG circuit 300 is depicted in the flow chart of FIG. 4. The AV delay is started in step S100 when a P-wave outside of refractory is sensed across the selected atrial sense electrode pair during the V-A escape interval (an A-EVENT) as determined in step S134 or an A-PACE pulse is delivered to the selected atrial pace electrode pair in step S118. The AV delay can be a PAV or SAV delay, depending upon whether it is started on an A-PACE or an A-EVENT, respectively, and is timed out by the SAV/PAV delay timer 372. The SAV or PAV delay is terminated upon a non-refractory RV-EVENT or LV-EVENT output by a ventricular sense amplifier prior to its time-out.

The post-event timers 374 are started to time out the post-ventricular time periods and the TRIG_PACE window, and the V-A escape interval timer 370 is started to time out the V-A escape interval in step S104 if the SAV or PAV delay

electrodes, then the A-PACE pulse is delivered across the selected RA pace electrode pair in step S118, the AV delay is set to PAV in step S120, and the AV delay is commenced by AV delay timer 372.

If a non-refractory A-EVENT is generated as determined in steps S122 and S134, then the V-A escape interval is terminated. The ABP and ARP are commenced by post-event timers 374 in step S134, the AV delay is set to the SAV in step S138, and the SAV delay is started in step S100 and timed out by SAV/PAV delay timer 372.

Assuming that the normal activation sequence is sought to be restored, a programmed SAV and PAV delay corresponding to a normal AV conduction time from the AV node to the bundle of His are used or a calculated SAV and PAV delay is calculated in relation to the prevailing sensor rate or sensed intrinsic heart rate and are used by SAV/PAV delay timer 372.

If an RV-EVENT or LV-EVENT or a collective V-EVENT sensed across the RV tip sense electrode and the LV sense electrode (for simplicity, all referred to as a V-EVENT) is detected in step S123 during the time-out of the V-A escape interval, then, it is determined if it is a non-refractory V-EVENT or a refractory V-EVENT in step S124. If an RV-EVENT or LV-EVENT (collectively a V-EVENT) is sensed during the time-out of the V-A escape interval in step S123, then, it is determined if it is a non-refractory V-EVENT or a refractory V-EVENT in step S124. If the V-EVENT is determined to be a refractory V-EVENT in step S124, then it is employed in the CVRP processing step S126 which is described in detail in the above-referenced application, Serial No. 09/439,244. If the V-EVENT is determined to be a non-refractory V-EVENT in step S124, then the V-A escape interval is restarted, and the post-ventricular time periods are restarted in step S128.

In step S130, it is determined whether a triggered pacing mode is programmed to be operative during the V-A escape interval. If one is programmed on, then it is undertaken and completed in step S132 (FIGs. 6A-6B). If triggered pacing is not programmed on as determined in step S130, then no ventricular pacing is triggered by the sensed non-refractory V-EVENT during the V-A escape interval. The time-out of

current pathways can develop between the active electrodes that can cause aberrant conduction pathways in the heart and can lead to oxidation or other deterioration of the pace/sense electrodes.

In addition, when a pacing system is implanted, the physician undertakes a work-up of the patient to determine the pacing energy and sensing thresholds that are sufficient to capture the heart and to distinguish true P-waves and R-waves from muscle artifacts and ambient electrical noise. If LV-PACE and RV-PACE pulses are delivered simultaneously, there may be a current contribution from the highest voltage active electrode delivering the highest voltage pulse to the lower voltage active electrode delivering the lower voltage pulse. The contribution may be sufficient to lower the pacing threshold at the lowest voltage active electrode. Then, at a later time, the programmed mode may be changed by eliminating or lowering the voltage of the highest voltage pacing pulse, and capture may be lost at the lowest voltage active pacing electrode.

As shown in FIG. 5, the IPG circuit 300 of FIG. 3 can be programmed to either only deliver a single RV-PACE or LV-PACE (V-PACE1) or the pair of RV-PACE and LV-PACE pulses (V-PACE1 and V-PACE2) separated by the VP-VP delay timed out by V-V delay timer 366. If delivery of only a single RV-PACE or LV-PACE is programmed as determined in step S200, then it is delivered in step S202.

In accordance with the present invention, the LV-PACE pulse is delivered across the active LV pace electrode 50 and the indifferent ring RV (IND_RV) pace electrode 38 in a trans-ventricular pacing path 60 (shown schematically in FIG. 2) encompassing the bulk of the LV and intraventricular septum separating the pace/sense electrodes. Although the active RV pace electrode 40 could be programmed to be paired as the indifferent electrode with the active LV pace electrode 50 it is generally not desirable to do so since both are of relatively small surface area, and it is usually desirable to provide a relatively large indifferent electrode surface area to function as an anode.

and LV sense electrode 50) can be programmed. The selection of the sensing vectors would depend upon heart condition and the selection of the pacing pulse pathways.

The IPG circuit 300 can be separately programmed in one of three triggered pacing modes designated VS/VP, VS/VP-VP or VS-VP triggered modes for each of steps S114 and S132. In the VS/VP triggered pacing mode, a V-PACE1 is delivered without delay upon a RV-EVENT or LV-EVENT to the RV or LV pacing pathway, respectively. In the VS/VP-VP triggered pacing mode, the V-PACE1 is delivered without delay upon a RV-EVENT or LV-EVENT to the selected RV or LV pacing electrode pair, respectively, and a V-PACE2 is delivered to the other of the selected LV or RV pacing electrode pair after the VS/VP-VP delay times out. In the VS-VP pacing mode, a RV-EVENT or the LV-EVENT starts time-out of a VS-VP delay, and a single pacing pulse (designated V-PACE2) is delivered to the selected LV or the RV pace electrode pair, respectively, when the VS-VP delay times out.

The TRIG_PACE time window started by a prior V-EVENT or V-PACE must have timed out in step S300 prior to delivery of any triggered ventricular pacing pulses. If it has not timed out, then triggered pacing cannot be delivered in response to a sensed V-EVENT. If the TRIG_PACE window has timed out, it is then restarted in step S302, and the programmed triggered pacing modes are checked in steps S304 and S316.

When IPG circuit 300 is programmed in the VS/VP-VP triggered mode as determined in step S304, the RV-EVENT or LV-EVENT triggers the immediate delivery of a respective RV-PACE or a LV-PACE or a programmed one of the RV-PACE or a LV-PACE across the programmed bipolar or unipolar RV and LV pace electrode pair, respectively, in step S306 as V-PACE1. Under certain circumstances, it is desirable to always deliver V-PACE1 to a designated RV or LV pace electrode pair, regardless of whether a RV-EVENT and LV-EVENT is sensed.

Then, a VS/VP-VP delay is started in step S308 and timed out in step S310. The VS/VP-VP delay is specified as a VP-VP delay when the RV-EVENT is sensed and the RV-PACE is V-PACE1 and the LV-PACE is V-PACE2. The VS/VP-VP delay is specified as a VP-VP delay when the LV-EVENT is sensed and the LV-

illustrating the operating modes of the IPG circuit 300 of FIG. 3 in a variety of bi-atrial or bi-ventricular pacing modes in accordance with a further embodiment of the invention selectively employing steps of FIGs. 4 through 6A-6B therein. It will be assumed, for example, that the AV synchronous pacing DDD(R) mode is changed to an atrial or ventricular demand, and triggered pacing mode. When FIGS. 4 through 6A-6B are incorporated into steps of FIG. 7 as described below, it will be understood that references to the ventricles (V) in those flow chart steps are appropriate to the bi-ventricular pacing system and method. However, references to the atria (A) can be substituted for the references to the ventricles (V) in those flow chart steps for an understanding of a bi-atrial pacing system and method in accordance with the present invention, where the LA-PACE pulse is delivered across a LA pace electrode pair comprising the active LA pace electrode 64 and the indifferent ring RA (IND_RA) pace electrode 21.

In step S400, the pacing escape interval started in step S418 from a prior R-SENSE or L-SENSE or previously delivered R-PACE or L-PACE (PACE1) is timing out. If the escape interval times out, then the TRIG-PACE window and the post-event time periods, including a conditional refractory period (CRP), the URI and the refractory period (RP) are commenced and timed out in step S402. At the same time, at least a PACE1 pacing pulse is delivered to one of the RHC or LHC in step S404, and the escape interval is restarted in step S418. Step S404 is completed in accordance with the steps of FIG. 5 as described above to either deliver a PACE1 to the selected RHC or LHC pace electrodes or to deliver both PACE1 and PACE2 to both the selected RHC and LHC pace electrodes in a programmed right-to-left or left-to right sequence separated by a programmed P-P delay.

A sense EVENT that is output by any of the RHC or LHC or the trans-chamber sense amplifier during the escape interval in step S402 is characterized as a refractory or non-refractory sense EVENT in step S406. If it is a refractory sense EVENT, then the CRP processing steps are followed as described in the above-referenced `(P8398) application to determine if it falls within or follows the time-out of the CRP and by how much the post-event time periods are to be continued or

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, therefore, that other expedients known to those of skill in the art or disclosed herein may be employed.

It will be understood that certain of the above-described structures, functions and operations of the pacing systems of the preferred embodiments are not necessary to practice the present invention and are included in the description simply for completeness of an exemplary embodiment or embodiments. It will also be understood that there may be other structures, functions and operations ancillary to the typical operation of such pacing systems that are not disclosed and are not necessary to the practice of the present invention. In addition, it will be understood that specifically described structures, functions and operations set forth in the above-listed, commonly assigned and co-pending patent applications can be practiced in conjunction with the present invention, but they are not essential to its practice.

In the following claims, means-plus-function clauses are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures.

It is therefore to be understood, that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described without actually departing from the spirit and scope of the present invention.

timing out said pacing interval from a right or left heart chamber sense event signal; and

upon a left heart chamber sense event signal, selectively delivering one of a right heart chamber pacing pulse across said right heart chamber active and indifferent pace/sense electrodes and a left heart chamber pacing pulse across said left heart chamber active pace/sense electrode and said right heart chamber indifferent pace/sense electrodes.

3. The method of Claim 2, further comprising the steps of:

timing out a triggered pacing delay from the providing of a right heart chamber sense event signal or a left heart chamber sense event signal or the timing out of the pacing interval; and

at the time-out of the triggered pacing delay:

selectively generating and delivering the left heart chamber pacing pulse across said left heart chamber active pace/sense electrode and said right heart chamber indifferent pace/sense electrodes when said right heart chamber pacing pulse is delivered across said right heart chamber active and indifferent pace/sense electrodes at the start of the triggered pacing delay; and

selectively generating and delivering the right heart chamber pacing pulse across said right heart chamber active pace/sense and indifferent electrodes when said left heart chamber pacing pulse is delivered across said left heart chamber active pace/sense electrode and said indifferent right heart chamber pace/sense electrode at the start of the triggered pacing delay.

4. The method of Claim 3, wherein the right heart chamber comprises the right atrium and the left heart chamber comprises the left atrium.

5. The method of Claim 3, wherein the right heart chamber comprises the right ventricle and the left heart chamber comprises the left ventricle.

9. The pacemaker of Claim 8, further comprising:

left heart chamber sensing means for sensing spontaneous cardiac depolarizations across the right heart chamber and left heart chamber active pace/sense electrodes and providing a left heart chamber sense event signal; and wherein:

said escape interval timing means further comprises means for timing out said pacing interval from a right or left heart chamber sense event signal; and

said pacing pulse generating means is operable upon provision of a left heart chamber sense event signal for selectively delivering one of a right heart chamber pacing pulse across said right heart chamber active and indifferent pace/sense electrodes and a left heart chamber pacing pulse across said left heart chamber active pace/sense electrode and said right heart chamber indifferent pace/sense electrodes.

10. The pacemaker of Claim 9, wherein said pulse generating means further comprises

triggered pacing delay timing means for timing out a triggered pacing delay from the providing of a right heart chamber sense event signal or a left heart chamber sense event signal or the timing out of the pacing interval; and wherein:

said pulse generating means is operable at the time out of the triggered pacing delay to selectively generate and deliver the left heart chamber pacing pulse across said left heart chamber active pace/sense electrode and said right heart chamber indifferent pace/sense electrodes when said right heart chamber pacing pulse is delivered across said right heart chamber active and indifferent pace/sense electrodes at the start of the triggered pacing delay and to selectively generate and deliver the right heart chamber pacing pulse across said right heart chamber active pace/sense and indifferent electrodes when said left heart chamber pacing pulse is delivered across said left heart chamber active pace/sense electrode and said indifferent right heart chamber pace/sense electrode at the start of the triggered pacing delay.

selectively generating and delivering a right ventricular pacing pulse across said right ventricular active and indifferent pace/sense electrodes at the time-out of said pacing escape interval; and

selectively generating and delivering a left ventricular pacing pulse across said left ventricular active pace/sense electrode and said right ventricular indifferent pace/sense electrodes at the time-out of said pacing escape interval.

16. The method of Claim 15, further comprising the step of:

sensing spontaneous cardiac depolarizations across the right ventricular and left ventricular active pace/sense electrodes and providing a left ventricular sense event signal; and the timing step further comprises the step of:

timing out a pacing escape interval establishing a pacing rate from a right or left ventricular sense event signal;

17. A pacemaker for improving the hemodynamic efficiency of a sick heart suffering from conduction delays in conducting spontaneous or evoked depolarizations originating in one of the right or left heart chamber to the other of the left or right heart chamber comprising:

right heart lead means for locating active and indifferent right heart chamber pace/sense electrodes in relation with the right heart chamber; and

left heart lead means for locating an active left heart chamber pace/sense electrode in relation with the left heart chamber; and

an implantable pulse generator coupled to said right and left heart lead means and comprising:

right heart chamber depolarization sensing means coupled with said right heart chamber lead means for sensing spontaneous cardiac depolarizations originating in the right heart chamber and conducted cardiac depolarizations originating in the left heart chamber due to a spontaneous cardiac depolarization or delivery of a left heart pacing pulse to the left heart chamber and for providing

depolarizations originating in one of the right or left heart chamber to the other of the left or right heart chamber comprising:

right heart lead means for locating active and indifferent right heart chamber pace/sense electrodes in relation with the right heart chamber;

left heart lead means for locating an active left heart chamber pace/sense electrode in relation with the left heart chamber;

an implantable pulse generator having a housing bearing an indifferent housing pace/sense electrode, said implantable pulse generator further comprising:

right heart chamber depolarization sensing means coupled with said active right heart chamber pace/sense electrode and one of said indifferent right heart electrode or housing pace/sense electrodes for sensing spontaneous cardiac depolarizations originating in the right heart chamber and conducted cardiac depolarizations originating in the left heart chamber due to a spontaneous cardiac depolarization or delivery of a left heart pacing pulse to the left heart chamber and for providing a right heart chamber sense event signal in response to either a sensed spontaneous or conducted cardiac depolarization;

left heart chamber depolarization sensing means coupled with said active left heart chamber pace/sense electrode and one of said active or indifferent right heart or indifferent housing pace/sense electrodes for sensing spontaneous cardiac depolarizations originating in the left heart chamber and conducted cardiac depolarizations originating in the right heart chamber due to a spontaneous cardiac depolarization or delivery of a right heart pacing pulse to the right heart chamber and for providing a left heart chamber sense event signal in response to either a sensed spontaneous or conducted cardiac depolarization;

right heart pacing pulse output means coupled with said right heart chamber lead means and selectively responsive to an applied right heart chamber pace trigger signal for generating and delivering a right heart pacing pulse across said active right heart pace/sense electrode and one of said indifferent right heart or housing pace/sense electrodes to evoke a right heart chamber depolarization;

left heart chamber depolarization sensing means coupled with said active left heart chamber pace/sense electrode and one of said active or indifferent right heart chamber pace/sense electrodes for sensing spontaneous cardiac depolarizations originating in the left heart chamber and conducted cardiac depolarizations originating in the right heart chamber due to a spontaneous cardiac depolarization or delivery of a right heart pacing pulse to the right heart chamber and for providing a left heart chamber sense event signal in response to either a sensed spontaneous or conducted cardiac depolarization;

right heart pacing pulse output means coupled with said right heart chamber lead means and selectively responsive to an applied right heart chamber pace trigger signal for generating and delivering a right heart pacing pulse across said active right heart chamber pace/sense electrode and one of said indifferent right heart or housing pace/sense electrodes to evoke a right heart chamber depolarization;

left heart pacing pulse output means coupled with said right and left heart chamber lead means and selectively responsive to an applied left heart chamber pace trigger signal for generating and delivering a left heart pacing pulse between said active left heart chamber and said indifferent right heart chamber pace/sense electrodes to evoke a left heart chamber depolarization; and

escape interval timing means for timing an escape interval establishing a pacing rate and providing one or both of the right and left heart chamber pace trigger signals at the time-out of the escape interval, the escape interval timing means further comprising reset means for restarting the timing of the escape interval upon provision of a pace trigger signal and upon provision of one of the right or left heart chamber sense event signals that is not refractory.

20. In a multi-site cardiac pacemaker, a method of selectively sensing spontaneous cardiac depolarizations in the right and left ventricles and delivering pacing pulses to the right and left heart ventricles for improving the hemodynamic efficiency of a sick heart suffering from conduction delays in conducting spontaneous

a bipolar right ventricular lead adapted to be advanced into the right ventricle to locate a right ventricular active pace/sense electrode and indifferent pace/sense electrode in relation to the right ventricle;

an atrial lead adapted to be advanced to the atria to locate atrial pace/sense electrodes in relation to the atria; and

a pulse generator comprising:

an atrial sense amplifier coupled to the atrial lead for sensing spontaneous atrial depolarizations and providing atrial sense event signals;

an AV delay timer for timing out an AV delay from the atrial sense event signals that are characterized as non-refractory;

a right ventricular sense amplifier coupled to the right ventricular lead for sensing spontaneous cardiac depolarizations in the right ventricle and providing right ventricular sense event signals;

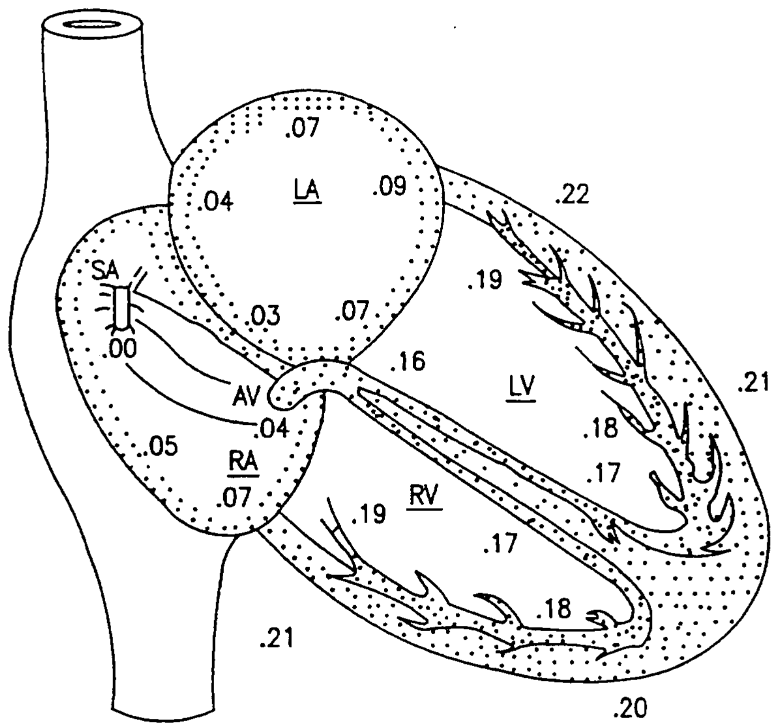
a left ventricular sense amplifier coupled to the right and left ventricular leads for sensing spontaneous cardiac depolarizations in the left ventricle and providing left ventricular sense event signals;

an escape interval timer for timing out a V-A escape interval establishing a pacing rate from a selected one of the right and left ventricular sense event signals occurring during the AV delay or the V-A escape interval that is characterized as non-refractory;

ventricular pacing pulse generating means operable at the time-out of the AV delay for delivering a first pacing pulse either as a right ventricular pacing pulse across the active right ventricular pace/sense electrode and a selected indifferent pacing electrode to evoke a right ventricular depolarization or as a left ventricular pacing pulse across said active left ventricular pace/sense electrode and said indifferent right ventricular pace/sense electrode to the left ventricle to evoke a left ventricular depolarization; and

means responsive to delivery of the first pacing pulse for restarting the timing out of the V-A escape interval.

10


.07
LA
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SA
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AV
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RA
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RV
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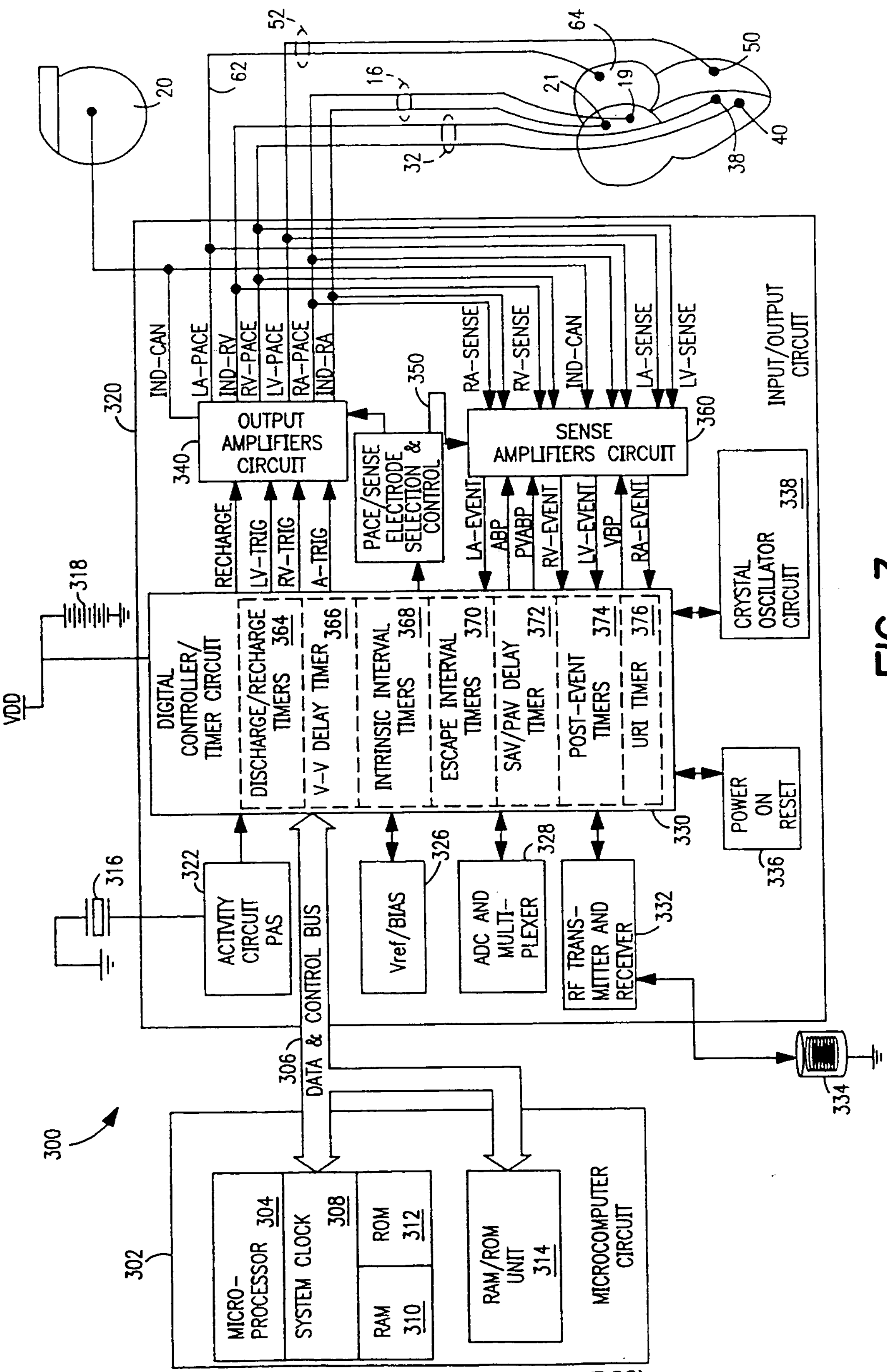
FIG. 1



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62
52
16
32
64
21
19
50
40
38
IND-CAN
LA-PACE
IND-RV
RV-PACE
LV-PACE
RA-PACE
IND-RA
350
RA-SENSE
RV-SENSE
IND-CAN
LA-SENSE
LV-SENSE
320
OUTPUT AMPLIFIERS CIRCUIT
340
PACE/SENSE ELECTRODE SELECTION & CONTROL
SENSE AMPLIFIERS CIRCUIT
360
INPUT/OUTPUT CIRCUIT
RECHARGE
LV-TRIG
RV-TRIG
A-TRIG
LA-EVENT
ABP
PVABP
RV-EVENT
LV-EVENT
VBP
RA-EVENT
CRYSTAL OSCILLATOR CIRCUIT 338
318
VDD
DIGITAL CONTROLLER/ TIMER CIRCUIT
DISCHARGE/RECHARGE TIMERS 364
V-V DELAY TIMER 366
INTRINSIC INTERVAL TIMERS 368
ESCAPE INTERVAL TIMERS 370
SAV/PAV DELAY TIMER 372
POST-EVENT TIMERS 374
URI TIMER 376
330
POWER ON RESET
336
316
322
ACTIVITY CIRCUIT PAS
326
Vref/BIAS
328
ADC AND MULTI-PLEXER
RF TRANS-MITTER AND RECEIVER
332
334
DATA & CONTROL BUS
306
300
302
MICRO-PROCESSOR 304
SYSTEM CLOCK 308
RAM 310
ROM 312
RAM/ROM UNIT 314
MICROCOMPUTER CIRCUIT

FIG. 3

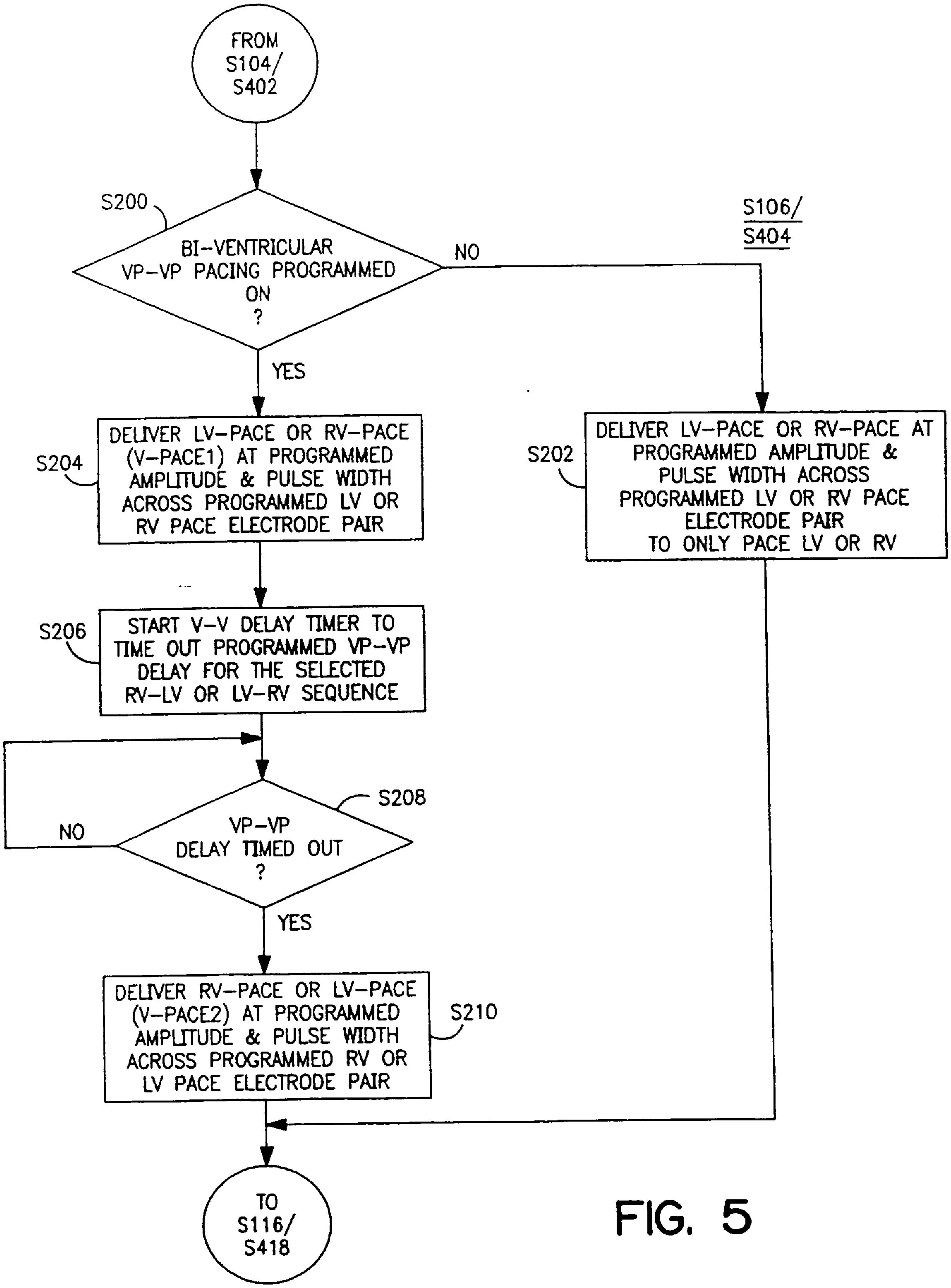
FROM S104/ S402
S200
BI-VENTRICULAR VP-VP PACING PROGRAMMED ON ?
NO
S106/ S404
YES
S204
DELIVER LV-PACE OR RV-PACE (V-PACE1) AT PROGRAMMED AMPLITUDE & PULSE WIDTH ACROSS PROGRAMMED LV OR RV PACE ELECTRODE PAIR
S202
DELIVER LV-PACE OR RV-PACE AT PROGRAMMED AMPLITUDE & PULSE WIDTH ACROSS PROGRAMMED LV OR RV PACE ELECTRODE PAIR TO ONLY PACE LV OR RV
S206
START V-V DELAY TIMER TO TIME OUT PROGRAMMED VP-VP DELAY FOR THE SELECTED RV-LV OR LV-RV SEQUENCE
S208
NO
VP-VP DELAY TIMED OUT ?
YES
DELIVER RV-PACE OR LV-PACE (V-PACE2) AT PROGRAMMED AMPLITUDE & PULSE WIDTH ACROSS PROGRAMMED RV OR LV PACE ELECTRODE PAIR
S210
TO S116/ S418

FIG. 5

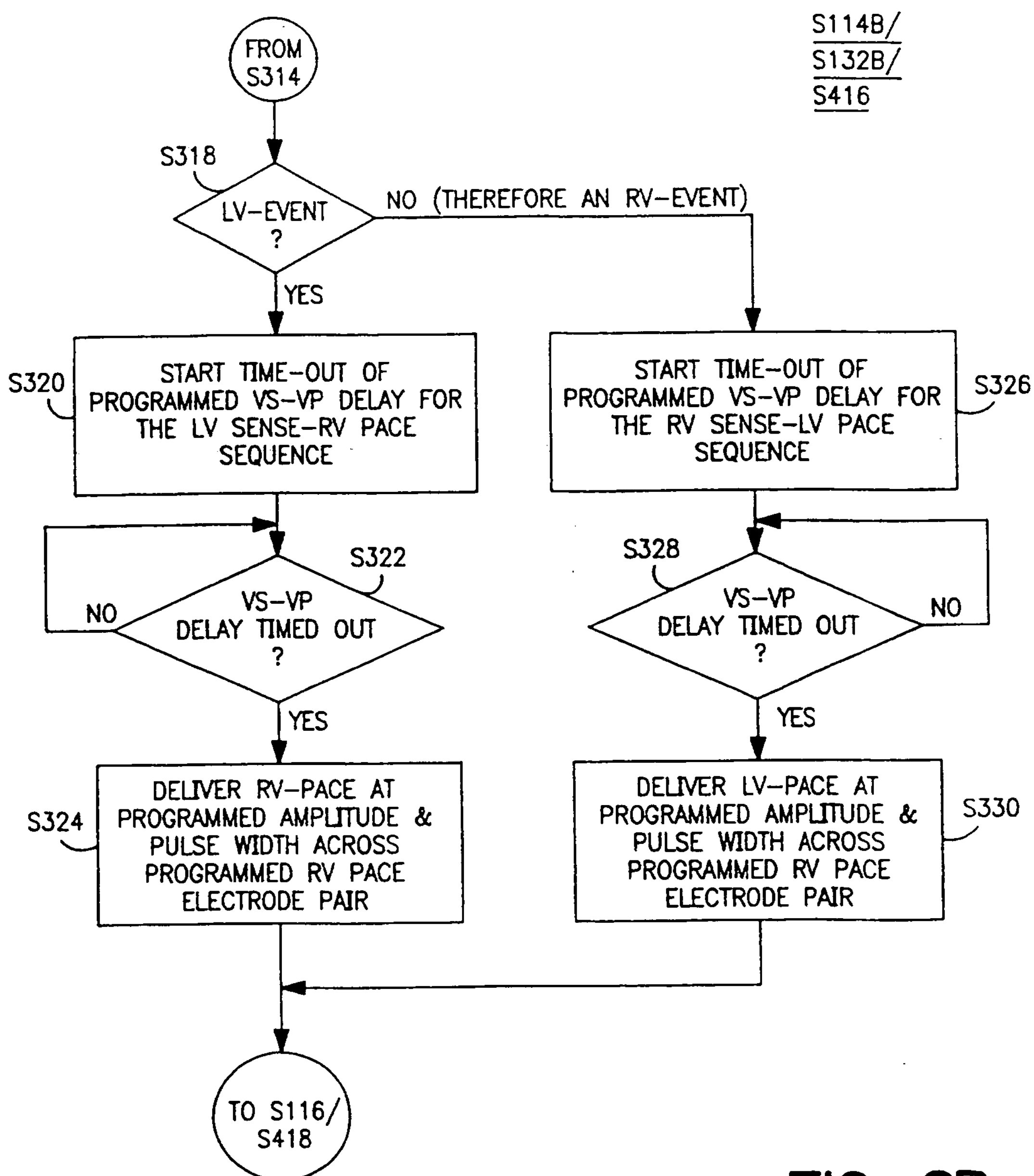

FIG. 6B

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/29544

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/362

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 99 55415 A (MEDTRONIC) 4 November 1999 (1999-11-04) the whole document	8-14, 17-23
Y	WO 99 13941 A (SULZER INTERMEDICS) 25 March 1999 (1999-03-25) page 5, line 31 -page 6, line 2	8-14, 17-23

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 February 2001	22/02/2001

Name and mailing address of the ISA	Authorized officer
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